

## **REMARKS/ARGUMENTS**

### **1. Remarks on the amendment**

Claims 1-5, 7 and 9-10 have been canceled. New Claims 11-16 have been added to more specifically define Applicant's claimed invention.

Antecedent basis can be found in the Specification and claims as filed. More specifically, antecedent basis of new Claim 11 can be found on page 20, lines 13-15 and on page 24, lines 9 to 24.

Applicant particularly submits that Ceteareth-20 in the lotion described in Example 2 of the Specification is a commercial product name, and this product is a polyoxyethylene ether of cetyl and stearyl alcohol (see Exhibit, MSDS of the commercial product). Therefore, the chemical name of this component is used in Claim 11, instead of the product name.

Applicant respectfully submits no new matter is introduced by the amendment.

### **2. Entitlement to the Claimed Priority**

Applicant submits that the instant composition as defined by the new independent Claim 11 is disclosed in the parent application Serial No. 09/976,915, which was filed on October 12, 2001. Therefore, Applicant's claimed invention entitles priority date of October 12, 2001.

### **3. Response to the Rejections of under 35 USC §112**

Claims 1-5, 7 and 9-10 have been canceled, therefore, this rejection is moot.

### **4. Response to the Rejection under 35 USC §103(a)**

Claims 1-5, 7 and 9-10 have been rejected under 35 U.S.C. §103(a) as being

unpatentable over Komer (U.S. 5,773,422) in view of Evans (EP 0137 627B1). This rejection is respectfully traversed by the amendment.

Claims 1-5, 7 and 9-10 have been canceled. Applicant's remarks below are in reference to new Claims 11-16.

Applicant submits that nothing in the art of record teaches or suggests the subject matter positively recited in the new independent Claim 11. As recited in independent Claim 11, Applicant's claimed dermatological composition consisting of an avermectin compound in a concentration from about 0.05% to 0.2% (w/v) in a lotion comprising glycerin, hydrogenated polyisobutene, cetearyl alcohol, polyoxyethylene ether of cetyl and stearyl alcohol, macadamia nut oil, dimethicone, tocopheryl acetate, stearoxytrimethylsilane, stearyl alcohol, panthenol, farnesol, benzyl alcohol, phenoxyethanol, acrylates/C10-30 alkyl acrylate crosspolymer, sodium hydroxide, citric acid, and water.

As demonstrated with extensive data in the Specification, the instant dermatological composition is not only effective in treating transient acantholytic dermatitis, acne miliaris necrotica, acne varioliformis, perioral dermatitis, acneiform eruptions, acne vulgaris, or seborrheic dermatitis, but also does not cause skin irritation, or increase of skin sensitivity after daily use of the instant composition for a substantial period of time up to several months (see Examples 4-14, particularly Example 9). Therefore, it has strong clinical advantages in treating these dermatological conditions.

Komer fails to teach Applicant's claimed dermatological composition defined in Claim 11. Komer teaches a pour-on formula comprising 0.5% of Ivermectin and at least 5% of N-methylpyrrolidone, 2-pyrrolidone or their mixtures for treatment of animals against ectoparasites (Abstract and Examples 15-16).

As shown in the references submitted in Applicant's response dated October 3, 2007, N-methylpyrrolidone can cause itching, redness, scaling and hives of skin. Similarly, 2-pyrrolidone may result in irritation upon contacting with skin. Therefore, Komer's formulations including N-methylpyrrolidone and/or 2-pyrrolidone together with avermectin for treatment of ectoparasites is not suitable

for treating dermatological conditions, particularly for daily use for a prolonged period of time. In this context, it is apparent that Komer teaches away from Applicant's claimed invention.

Evans et al teach a pour-on formulation for control of parasites, which comprises an endoparasiticide including ivermectin and a carrier comprising at least one saturated aliphatic carboxylate ester of a mono alkyl ether of a mono- or poly- alkylene glycol. Evans et al teach their formulation has improved efficacy, freedom from unacceptable skin reactions even when applied to sensitive breeds of animals and long shelf life.

However, Evans et al fail to teach Applicant's claimed dermatological composition, which does not contain Evans' key component of saturated aliphatic carboxylate ester of a mono alkyl ether of a mono- or poly- alkylene glycol, yet can be used for prolonged period time without skin irritation or increase skin sensitivity.

Since neither reference teaches Applicant's claimed dermatological composition, one of ordinary skill in the art would not be motivated to combine Komer and Evans et al in order to obtain Applicant's claimed composition. Even if one combines, one would not obtain Applicant's claimed composition.

Therefore, Applicant submits that Applicant's claimed dermatological composition defined in Claim 11 is unobvious in view of the prior art of record.

With regard to Claims 12-16, these claims are dependent upon independent Claim 11. Under the principles of 35 U.S.C. §112, 4th paragraph, all of the limitations of each independent claim are recited in its respective dependent claims. As described above, independent Claim 11 is not obvious, as such Claims 12-16 are submitted as being allowable over the art of record.

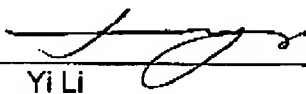
Accordingly, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. §103(a).

It is respectfully submitted that Claims 11-16, the pending claims, are now in condition for allowance and such action is respectfully requested.

Application No. 10/730,783  
Amdt. Dated March 26, 2008  
Reply to Office Action of October 26, 2007

Applicant's Agent respectfully requests direct telephone communication from the Examiner with a view toward any further action deemed necessary to place the application in final condition for allowance.

3/26/2008  
Date of Signature

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Updated May 23, 2007

## Cetareth-20

### Material Safety Data Sheet (MSDS)

#### 1. PRODUCT IDENTIFICATION

**Product Name:** cetareth-20  
**INCI Name:** cetareth-20  
**Synonyms:** polyoxyethylene ether of cetyl/stearyl alcohol  
**CAS Number:** 68439-49-6  
**EINECS Number:**  
**Origin:** synthetic

#### 2. PHYSICAL & CHEMICAL PROPERTIES

**Melting Point:** 40°C (104°F)  
**Boiling Point:** not applicable  
**Vapor Density, Air=1:** >1  
**Vapor Pressure:** <1 mmHg at 25°C  
**Specific Gravity:** not determined  
**Solubility in water:** dissolves in water & alcohols  
**pH Value:** 5 - 7 (10% solution)  
**Appearance & Odor:** white powder, no odor

#### 3. STABILITY & REACTIVITY

**Chemical Stability:** stable under normal conditions  
**Incompatibility:** May react with strong oxidizing agents  
**Hazardous Decomposition:** biodegradable; burning can produce carbon monoxide and carbon dioxide  
**Hazardous Polymerization:** will not occur

#### 4. HANDLING & STORAGE

Avoid contact with eyes. Wash thoroughly after handling. As with all chemicals, good industrial hygiene practices should be followed when handling this material.

Avoid freezing or excessive heat. Do not handle or store near an open flame, heat or other sources of ignition. Keep the container tightly closed and in a cool, well-ventilated place.

#### 5. ACCIDENTAL RELEASE MEASURES

Isolate spill area immediately. Keep unauthorized personnel away. Ventilate closed spaces before entering. Do not touch or walk through spilled material. Prevent entry into waterways, sewers, basements or confined areas. Surface may become slippery after spillage. Use vacuum or broom sweeping and remove to disposal container. If damp, flush with water.

#### 6. EXPOSURE CONTROLS & PERSONAL PROTECTION

**Respiratory Protection:** Where exposure likely exceeds acceptable criteria, use NIOSH/OSHA-approved respiratory equipment.  
**Protective Clothing:** Gloves recommended to prevent prolonged skin contact. Safety glasses, goggles, or face shield recommended for eye protection.

**Other Protective Measures:** Employees must practice good personal hygiene, washing exposed areas of skin several times daily and laundering contaminated clothing before re-use.

#### 7. HAZARDS IDENTIFICATION

**General:** no specific health hazards reported.  
**Inhalation:** no evidence from toxic effects from available information.

**Eye Contact:** no irritation is likely to occur; if symptoms develop seek medical attention.

**Skin Contact:** no irritation is likely to occur

**Ingestion:** no evidence from adverse effects from available information.

#### 8. FIRST AID MEASURES

**Eyes:** Irrigate eyes with a heavy stream of water for at least 20 minutes. Seek medical attention if symptoms persist.

**Skin:** Wash exposed areas of the body with plenty of water.

**Inhalation:** Remove from area of exposure. If breathing is difficult, give oxygen. Seek medical attention if symptoms persist.

**Ingestion:** Drink water. Do not induce vomiting. Consult medical personnel. Never give anything by mouth to an unconscious person.

#### 9. FIRE FIGHTING MEASURES

**Flash Point:** >175°C (>347°C)

**Extinguishing Media:** water spray, foam, carbon dioxide

**Fire Fighting Procedures:** Firefighters should wear full fire-fighting turn-out gear (full Bunker gear) including NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

#### 10. TOXICOLOGICAL INFORMATION

**Acute LD50:** not data available

**Dermal and Eye Irritation Test:** not data available

**Carcinogenicity:** not data available

**Mutagenicity:** not data available

#### 11. DISPOSAL CONSIDERATIONS

Storage and disposal must be in accordance with applicable local, state & federal disposal regulations. Characterization and compliance with applicable laws are the responsibility solely of the generator.

#### 12. TRANSPORT INFORMATION

**DOT Shipping Name:** Refer to corresponding hazard class

**ADR/RIC Code:** Refer to corresponding hazard class

**Sea Transport IMDG Code:** Refer to corresponding hazard class

**Air Transport IATA:** Refer to corresponding hazard class

#### 13. DISCLAIMER

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